



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61K 7/16</b>		A1	(11) International Publication Number: <b>WO 99/62472</b> (43) International Publication Date: 9 December 1999 (09.12.99)
(21) International Application Number: <b>PCT/US99/12325</b> (22) International Filing Date: 3 June 1999 (03.06.99)  (30) Priority Data: 60/087,850 3 June 1998 (03.06.98) US		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(71)(72) Applicant and Inventor: <b>WOLF, Robert, O. [US/US]; 1804 Farris Garden Path, Westlake, OH 44145 (US).</b> (74) Agent: <b>JAFFE, Michael, A.; Arter &amp; Hadden LLP, 1100 Huntington Building, 925 Euclid Avenue, Cleveland, OH 44115-1475 (US).</b>		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: <b>SYSTEM FOR WHITENING TEETH SURFACES</b>			
(57) Abstract A system for whitening teeth surfaces in the form a whitening strip. The strip has a plurality of layers including a base layer and a carrier layer. The carrier layer includes a whitening agent and an adhesive for applying the strip to teeth. The base layer is a flexible layer for supporting the carrier layer.			

BEST AVAILABLE COPY

***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## SYSTEM FOR WHITENING TEETH SURFACES

5

### Field of Invention

The present invention generally relates to a tooth whitening system, and more particularly to a system for applying a composition to teeth in order to whiten or bleach the surface of the teeth.

10

### Background of the Invention

Historically, a gradual darkening of the teeth has been accepted as a natural part of the aging process. Indeed, false teeth were often progressively darkened as a person aged to match an expected darkening of the teeth for a certain age. Relatively recent procedures have emerged to allow for whitening of the teeth, darkened by age, chemical 15 discoloration or the like. To this end, many people have veneers placed over their teeth or have their teeth chemically bleached. For many years, teeth whitening involved an in-office procedure. More recently, however, a variety of over-the-counter tooth whitening products and methods have become available, including technology such as boil and bite trays, non-moldable trays (which may cover both upper and lower teeth), foam trays, and the like. A 20 current representative technique includes the steps of: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, and trimming to exclude gingival coverage; and (4) instructing the patient to: (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (3) expectorate any excess bleaching solution, (4) change the bleaching 25 solution every 1 to 2.5 hours, and (5) remove the tray during meals. The foregoing steps can be complicated, time-consuming and inconvenient. The present invention addresses these and other drawbacks of prior art tooth whitening systems.

### Summary of the Invention

30

According to the present invention there is provided a system for applying a composition to teeth in order to whiten or bleach the surface of the teeth.

An advantage of the present invention is the provision of a tooth whitening system which is simple and convenient to use.

Still another advantage of the present invention is the provision of a tooth whitening system which is fast and effective.

5 Still another advantage of the present invention is the provision of a tooth whitening system which requires minimal time for application.

Still another advantage of the present invention is the provision of a tooth whitening system which does not require the use of a tray.

10 Yet another advantage of the present invention is the provision of a tooth whitening system which uses an adhesive as a carrier.

Yet another advantage of the present invention is the provision of a tooth whitening system which can be suitably customized to provide a whitening composition to only tooth surfaces.

15 Yet another advantage of the present invention is the provision of a tooth whitening system which is inexpensive to manufacture.

Still other advantages of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description, accompanying drawings and appended claims.

20 **Brief Description of the Drawings**

The invention may take physical form in certain parts and arrangements of parts, a preferred embodiment and method of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

25 Fig. 1 shows an enlarged perspective view of a whitening strip according to a preferred embodiment of the present invention;

Fig. 2 shows an enlarged perspective view of a whitening strip according to an alternative embodiment;

30 Fig. 3 shows a whitening strip, according to another embodiment of the present invention, as applied to the teeth;

Fig. 4 is a cross-sectional view of the whitening strip shown in Fig. 3, as

adhered to the teeth; and

Fig. 5 is a cut-away view of the whitening strip shown in Fig. 3.

#### Detailed Description of the Preferred Embodiment

5 Referring now to the drawings wherein the showings are for the purposes of illustrating a preferred embodiment of the invention only and not for purposes of limiting same, Fig. 1 shows a whitening strip 10 according to a preferred embodiment of the present invention. Whitening strip 10 is generally comprised of a base layer 20 and a carrier layer 30.

10 Carrier layer 30 is comprised of a dental bleaching or whitening agent and an adhesive. The whitening agent may take any number of forms, including hydrogen peroxide, carbamide peroxide, trichloroisocyanuric acid, tetrasodium pyrophosphate, chlorine dioxide, and sodium perborate. It should be appreciated that the combination of hydrogen peroxide and bleaching activators (such as trichloroisocyanuric acid and tetrasodium pyrophosphate) react to raise the pH of the system thereby producing perhydroxy radicals which are effective 15 bleaching agents. The required concentration of whitening agent will vary depending upon its reactivity. In a preferred embodiment of the present invention, a 3% hydrogen peroxide composition is used. It should be appreciated that a 16% carbamide peroxide composition is generally equivalent to a 5% hydrogen peroxide composition.

20 In an alternative embodiment of the present invention, the whitening agent may include a photo initiator, such as camphor quinone. A photo initiator makes the whitening agent light activated. Camphor quinone is activated by a visible light source, such as a halogen light (450 to 550 nm wave-length). Accordingly, the whitening agent could be activated by the use of a conventional dental bonding light, which is commonly found in most dental offices, or a dental bonding laser. It should also be appreciated that the whitening 25 agent could be formed such that it is activated by other means (e.g., salt).

The adhesive may take any number of forms. In this regard, the adhesive may take the form of nontoxic polymers, including natural or synthetic elastomers, such as polyisobutylene, styrene, butadiene, styrene isoprene block copolymers, acrylics, urethanes, silicones, styrene butadiene, copolymers, methyl acrylate copolymers, acrylic acid, 30 polyacrylates, and polysaccharides such as, karaya gum, tragacanth gum, pectin, guar gum, cellulose, and cellulose derivatives such as methyl cellulose, propyl cellulose, cellulose

acetate and the like. The term "adhesive" as used herein means a substance, inorganic or organic, natural or synthetic, that is capable of surface attachment to the intended application site.

Base layer 20 provides a backing material. The backing material preferably 5 takes the form of a flexible material, such as paper, a non-woven fabric or natural or synthetic polymer substance. The flexibility of the backing material allows whitening strip 10 to conform to the arrangement of a row of teeth. It should be appreciated that base layer 20 may include a plurality of layers of backing material.

The whitening agent is dispersed in the adhesive to form a carrier layer 32, 10 which is applied to base layer 20. It should be appreciated that a removable film layer (not shown) may be applied over carrier layer 30. The removable film layer suitably protects carrier layer 30 prior to application of whitening strip 10 to the teeth.

It should be appreciated that the present invention is similar to the composition and methods disclosed in United States Patent Nos. 5,234,957 and 5,332,576 (assigned to 15 Noven Pharmaceuticals, Inc. of Miami, Florida), except that a suitable tooth bleaching or whitening agent replaces the local anesthetic agents. Accordingly, the foregoing patents are fully incorporated herein by reference.

To use whitening strip 10, the film layer is removed and carrier layer 32 is adhered to the teeth in an appropriate manner. In this regard, whitening strip 10 has a width 20 dimension suitable to cover a row of teeth (upper or lower). Therefore, one whitening strip is applied to the upper set of teeth, while a second whitening strip is applied to the lower set of teeth. It should be appreciated that the length dimension of whitening strip 10 is determined by the amount of coverage desired. In this regard, the number of teeth which it is desired to whiten will determine the dimensions of whitening strip 10. For instance, it may be desired 25 to only whiten the front teeth, which are most easily seen by others. Accordingly, the length of whitening strip 10 can be reduced in this case, as compared to the case where it is desired to whiten all of the teeth. The duration of application of whitening strip 10 to the teeth will depend upon the type and concentration of the whitening agent, as well as the type and intensity of stain.

30 In the embodiment shown in Fig. 2 whitening strip 10' is shaped to fully cover the teeth, while avoiding contact with the gums. In this regard, a series of notches 40 are

formed to accommodate the gum line.

Figs. 3-5 illustrate yet another embodiment of the present invention. Fig. 3 shows the manner in which a whitening strip is applied to a set of teeth. In this embodiment, whitening strip 10" includes an active section A having a whitening agent, and an inactive section I that does not include a whitening agent. Active section A takes the general shape of the teeth (Fig. 5), so as to avoid contact with gum tissue when whitening strip 10" is applied to the teeth in the manner illustrated in Fig. 3. Inactive section is located above and below the active section A. In this respect, the upper inactive section will contact gum tissue, while the lower inactive section will contact the back surface of the teeth (Fig. 4). Adhesive is applied to both the active and inactive sections to adhere whitening strip 10" to the teeth and gum tissue.

The invention has been described with reference to a preferred embodiment. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. For instance, the whitening strip may include active ingredients other than whitening agents. It is intended that all such modifications and alterations be included insofar as they come within the scope of the invention or equivalents.

Having thus described the invention, it is now claimed:

1. A strip member for whitening teeth comprising:

a base layer; and

a carrier layer including a whitening agent, wherein said carrier layer is applied to the base layer.

2. A strip member according to claim 1, wherein said carrier layer further

comprises an adhesive.

3. A strip member according to claim 1, wherein said whitening agent comprises

at least one of : hydrogen peroxide, carbamide peroxide, trichloroisocyanuric acid, tetrasodium pyrophosphate, chlorine dioxide, and sodium perborate.

4. A strip member according to claim 1, wherein said whitening agent comprises

hydrogen peroxide and at least one bleaching activator.

5. A strip member according to claim 1, wherein said whitening agent includes a

photo initiator.

6. A strip member according to claim 5, where said photo initiator includes

camphor quinone.

7. A strip member according to claim 2, wherein said adhesive includes at least

one of : nontoxic polymers.

8. A strip member according to claim 7, wherein said nontoxic polymers include

at least one of natural and synthetic elastomers.

9. A strip member according to claim 8, wherein said natural and synthetic

polymers include at least one of: polyisobutylene, styrene, butadiene, styrene isoprene block copolymers, acrylics, urethanes, silicones, styrene butadiene, copolymers, methyl acrylate

copolymers, acrylic acid, polyacrylates, and polysaccharides such as, karaya gum, tragacanth gum, pectin, guar gum, , cellulose, and cellulose derivatives.

10. A strip member according to claim 1, wherein said base layer is formed of a flexible material.

11. A strip member according to claim 10, wherein said flexible material includes at least on or paper, a non-woven fabric, natural polymer, and synthetic polymer.

12. A strip member according to claim 1, wherein said whitening agent is dispersed in an adhesive.

13. A strip member according to claim 1, wherein said strip member further comprises a removable film layer to protect said carrier layer.

1/2

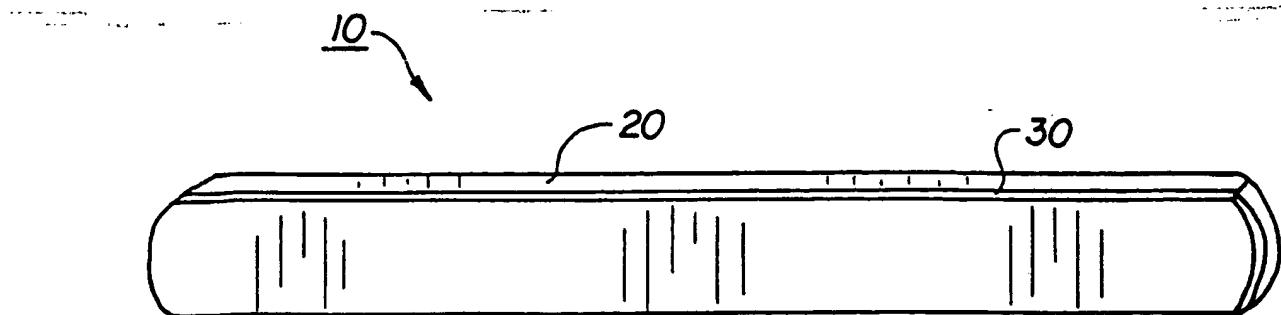


FIG. 1

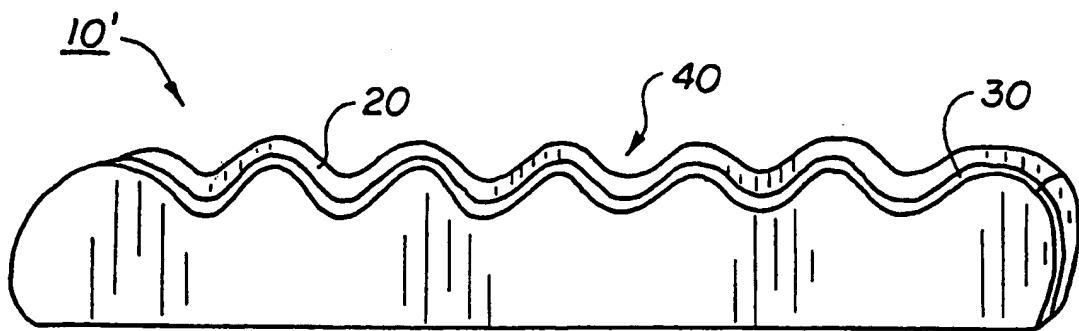


FIG. 2

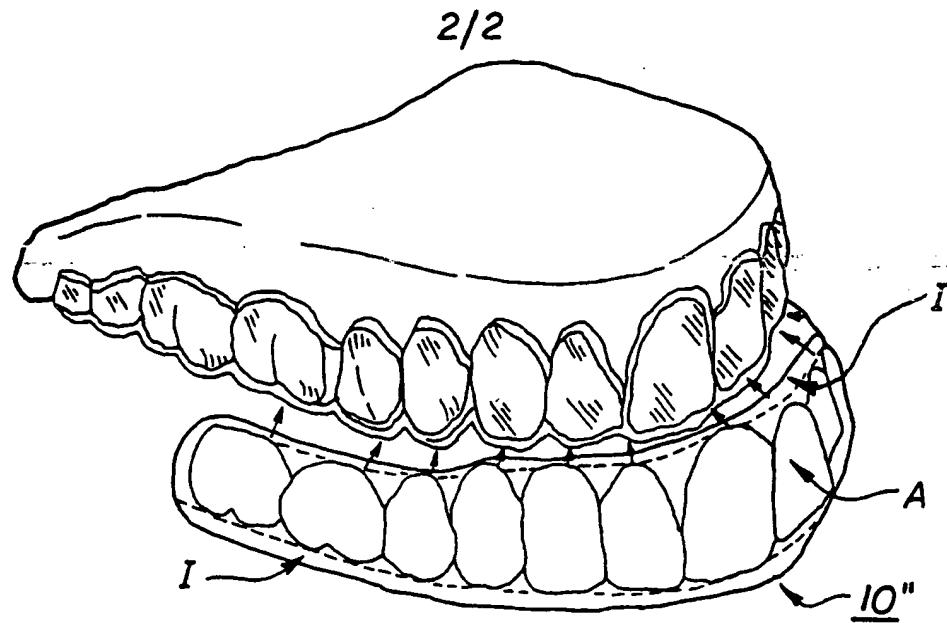


FIG. 3

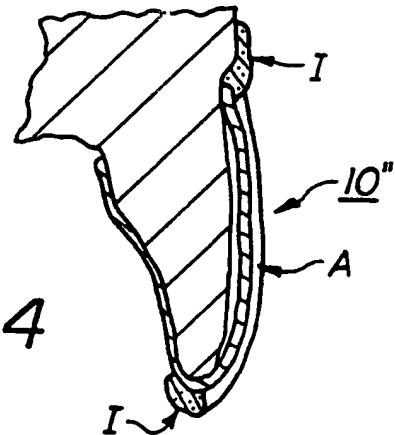


FIG. 4

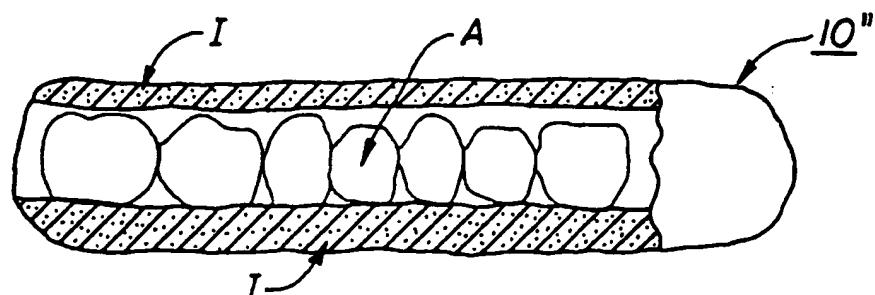


FIG. 5

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12325

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K/16

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 16488 A (SHOWA HATSUMEI KAISHA LTD ;GAGLIO THOMAS J (US); SANTORIELLO LUIGI) 22 June 1995 (1995-06-22) abstract page 3, line 22 -page 4, line 10 page 4, line 31 -page 5, line 27 page 6, line 15 - line 34 page 8, line 11 -page 9, line 8 page 11, line 14 -page 12, line 9 claims figures 4-7 ---	1,2,7,8, 10-12
Y	page 3, line 22 -page 4, line 10 page 4, line 31 -page 5, line 27 page 6, line 15 - line 34 page 8, line 11 -page 9, line 8 page 11, line 14 -page 12, line 9 claims figures 4-7 ---	3,4,9,13

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

17 September 1999

27/09/1999

Name and mailing address of the ISA  
European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.  
Fax: (+31-70) 340-3018

Authorized officer

Cielen, E

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12325

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PATENT ABSTRACTS OF JAPAN vol. 098, no. 005, 30 April 1998 (1998-04-30) & JP 10 017448 A (LION CORP), 20 January 1998 (1998-01-20) abstract & DATABASE WPI _____ Week 9814 Derwent Publications Ltd., London, GB; AN 98-148346 abstract ---	1-3,7, 10-12
Y	US 5 310 563 A (CURTIS JOHN ET AL) 10 May 1994 (1994-05-10) abstract column 3, line 8 -column 4, line 3 column 5, line 56 - line 65 column 7, line 16 - line 53 column 8, line 30 - line 56 ---	3,4,13
Y	US 3 688 406 A (PORTER WILLIAM I ET AL) 5 September 1972 (1972-09-05) abstract column 1, line 34 -column 3, line 9 column 3, line 27 - line 47 column 4, line 37 - line 46 ---	9
P,X	WO 98 55079 A (PROCTER & GAMBLE) 10 December 1998 (1998-12-10) abstract page 2, paragraph 1 page 3, paragraph 4 -page 4, paragraph 6 page 6, paragraph 5 -page 7, paragraph 2 page 9, paragraph 2 - paragraph 3 page 10, paragraph 5 -page 11, paragraph 1 page 18, paragraph 2 -page 19, paragraph 1 page 19, paragraph 5 -page 22, paragraph 2 figures 2-6 ---	1-3,7-13
A	WO 95 05416 A (BIEGAJSKI JAMES E ;VENKATRAMAN SUBBU S (US); SCOTT ANN M (US); CYG) 23 February 1995 (1995-02-23) abstract page 5, line 16 -page 6, line 13 page 11, line 26 -page 12, line 16 page 13, line 24 -page 15, line 27 page 58, line 3 - line 26 -----	

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 12325

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
See FURTHER INFORMATION SHEET PCT/ISA/210
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

The present claim 5 relates to a large number of possible compounds. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a small proportion of the compounds claimed. In the present case, claim 5 so lacks support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of claim 5 which appear to be supported and disclosed, namely those parts relating to the specifically named compound (claim 6, description p. 3, lines 19-25) and to the general principle of including a photo initiator.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/12325

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9516488	A	22-06-1995	US	5326685 A	05-07-1994
JP 10017448	A	20-01-1998		NONE	
US 5310563	A	10-05-1994	CA	2081232 A	26-04-1993
			US	5639445 A	17-06-1997
US 3688406	A	05-09-1972		NONE	
WO 9855079	A	10-12-1998	US	5894017 A	13-04-1999
			AU	7704198 A	21-12-1998
WO 9505416	A	23-02-1995	AU	7568394 A	14-03-1995
			CA	2169729 A	23-02-1995
			CN	1134163 A	23-10-1996
			EP	0717761 A	26-06-1996
			JP	9504810 T	13-05-1997
			US	5700478 A	23-12-1997

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

**BLACK BORDERS**

**IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

**FADED TEXT OR DRAWING**

**BLURRED OR ILLEGIBLE TEXT OR DRAWING**

**SKEWED/SLANTED IMAGES**

**COLOR OR BLACK AND WHITE PHOTOGRAPHS**

**GRAY SCALE DOCUMENTS**

**LINES OR MARKS ON ORIGINAL DOCUMENT**

**REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

**OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

**BLACK BORDERS**

**IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

**FADED TEXT OR DRAWING**

**BLURRED OR ILLEGIBLE TEXT OR DRAWING**

**SKEWED/SLANTED IMAGES**

**COLOR OR BLACK AND WHITE PHOTOGRAPHS**

**GRAY SCALE DOCUMENTS**

**LINES OR MARKS ON ORIGINAL DOCUMENT**

**REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

**OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image  
problems checked, please do not report these problems to  
the IFW Image Problem Mailbox.**